

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re
Diet Drug Litigation

Mary Andrus; *et al*,

Plaintiffs,

v.

Indevus Pharmaceuticals, Inc., F/K/A
Interneuron Pharmaceuticals, Inc.;
Wyeth, Inc., F/K/A American Home
Products Corporation;
Wyeth Pharmaceuticals, Inc. F/K/A
Wyeth-Ayerst Pharmaceuticals,
Inc., A Division Of American Home Products
Corporation; and Boehringer Ingelheim
Pharmaceuticals, Inc.,

Defendants.

CIVIL ACTION

NO. 04-10911 GAO
(and all related actions)

WYETH DEFENDANTS' MASTER AMENDED ANSWER

Defendants Wyeth¹ (formerly known as American Home Products Corporation (“AHPC”)) and Wyeth Pharmaceuticals Inc. (collectively, “Answering Defendants”), hereby amend each answer filed in each and every related diet drug product liability action to include the following defenses:

¹ On March 11, 2002, American Home Products Corporation changed its name to Wyeth. On March 22, 2002, Wyeth-Ayerst Pharmaceuticals Inc. changed its name to Wyeth Pharmaceuticals Inc.

GENERAL DENIAL

To the extent any allegation in the Complaint is not specifically admitted, it is denied in its entirety.

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred in whole or in part by the applicable statute of limitations, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Nationwide Settlement Agreement With American Home Products Corporation ("Settlement Agreement") approved by the United States District Court for the Eastern District of Pennsylvania.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred in whole or in part by the doctrine of laches, waiver and estoppel, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Settlement Agreement.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint is defective in that Plaintiffs have failed to join indispensable parties.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred in whole or in part by Plaintiffs' comparative and/or contributory negligence.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, were caused, solely or partially, or proximately caused by, some third person or third party for whom Answering Defendants are not legally responsible.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or product placed in the stream of commerce by, Answering Defendants.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged damages were the result of pre-existing conditions unrelated to any conduct of, or product placed in the stream of commerce by, Answering Defendants.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged damages were the result of an idiosyncratic reaction, which Answering Defendants could not reasonably foresee.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, and if they were caused by Pondimin or Redux, were caused in whole or in part by misuse or unintended use of the product.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, were caused by changes and/or alterations to Answering Defendants' products made by persons not within Answering Defendants' control.

TWELFTH AFFIRMATIVE DEFENSE

Answering Defendants provided complete and adequate warnings to Plaintiffs' prescribing physicians. Therefore, any claims by Plaintiffs for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred in whole or in part by the lack of a defect, as the pharmaceuticals ingested by Plaintiffs were properly prepared in accordance with the applicable standard of care.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' product liability causes of action are barred because the benefits of Pondimin and/or Redux outweighed the risks.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' product liability causes of action are barred because the relevant products were consistent with or exceeded consumer expectations.

SIXTEENTH AFFIRMATIVE DEFENSE

Based on the state of scientific, medical, and technological knowledge at the time Pondimin and/or Redux was marketed, the subject pharmaceuticals were reasonably safe for normal and foreseeable use at all relevant times.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Answering Defendants complied with all applicable state and federal statutes and with the requirements and regulations of the FDA.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims under Massachusetts law are barred by the doctrine of federal preemption.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against Answering Defendants are barred under Section 402A, comment k of the Restatement (Second) of Torts and Section 6 et seq. of the Restatement (Third) of Torts: Products Liability.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' strict liability claims cannot be maintained against a prescription drug manufacturer.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The damages recoverable by Plaintiffs, if any, must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or in part.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Answering Defendants expressly deny that any third party engaging in the acts alleged by Plaintiffs were acting as an agent or servant, or at the instruction or within the control of, Answering Defendants. Therefore, to the extent that Plaintiffs seek to recover for the acts or omissions of such third parties, Plaintiffs' claims are barred as a matter of law.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, from collateral sources.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Should Answering Defendants be held liable to Plaintiffs, which liability is specifically denied, Answering Defendants would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasors for the same injuries alleged in the Complaint.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any physical injuries that were proximately caused by any act or omission by Answering Defendants, and it is more likely than not that Plaintiffs will not contract any illness or injury from the alleged use of the products which are the subject of this action.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

All acts or omissions by Answering Defendants were undertaken in good faith without malice or recklessness, and were fully justified and reasonable under the circumstances.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to plead the claim of fraud with the requisite specificity required by law.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, Plaintiffs' punitive damages claims are barred by the Constitution of the United States and the Constitution of the Commonwealth of Massachusetts.

TWENTY-NINTH AFFIRMATIVE DEFENSE

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, Plaintiffs must prove a claim for punitive damages by proffering clear and convincing evidence of willful and malicious or wanton, reckless conduct, or by proffering evidence of a willing or knowing violation by Answering Defendants of the Massachusetts Consumer Act, Mass. Gen. Laws ch. 93A, §9, under Massachusetts and/or federal law. No act or omission by Answering Defendants was malicious, willful, wanton,

reckless, or grossly negligent or in willful or knowing violation of the Consumer Act; therefore any award of punitive damages is barred.

THIRTIETH AFFIRMATIVE DEFENSE

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, punitive damages are unjust, discriminatory, unconstitutionally vague and/or overly broad, because there is no explicit standard by which they can be measured or determined.

THIRTY-FIRST AFFIRMATIVE DEFENSE

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, with respect to Plaintiffs' demand for punitive damages, Answering Defendants specifically incorporates by reference all standards or limitations regarding the determination and enforceability of punitive damages awards which arose in the U.S. Supreme Court decisions of *BMW of North America v. Gore*, 116 U.S. 1589 (1996) and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 123 S.Ct. 1513 (2003).

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are subject to dismissal or transfer on the basis of improper venue.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' eligibility to exercise an Intermediate and/or Back-End Opt-Out right and file an individual lawsuit against Answering Defendants is subject to challenge by Answering Defendants pursuant to Section IV.D.3.c of the Settlement Agreement. Answering Defendants reserve the right to challenge Plaintiffs' eligibility if and when Answering Defendants discover that Plaintiffs are not eligible to exercise such an Intermediate Opt-Out right.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because, at all relevant times, plaintiffs were knowledgeable purchasers who were aware of the alleged hazards of Redux and/or Pondimin and, therefore, Plaintiffs expressly or impliedly assumed the risk of any alleged damages.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Redux and/or Pondimin.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' recovery, if any, should be reduced by the comparative negligence, fault, responsibility or causation attributable to third parties, for whom Answering Defendants are not legally responsible.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because Plaintiffs were not foreseeable users of the product.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because Plaintiffs' alleged damages were not caused by any failure to warn on the part of Answering Defendants.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred in whole or in part by Plaintiffs' failure to assert a safer design for Redux and/or Pondimin.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred in whole or in part because Answering Defendants complied with all applicable statutes and with the requirements and regulations of the FDA.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because they did not reasonably rely on any alleged express or implied warranty.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs failed to notify Answering Defendants of any alleged breach of warranty within a reasonable time after they discovered or should have discovered any such alleged breach and are, therefore, barred from recovery for such claims.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because Plaintiffs suffered no physical injury from Redux and/or Pondimin.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs impermissibly seek to impose liability on conduct protected from liability by the First Amendment to the United States Constitution.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for punitive damages are in contravention of Answering Defendants' rights under the Commerce Clause of Article I, Section 8 of the United States Constitution, the Contracts Clause of Article I, Section 10 of the United States Constitution, and the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution,

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recovery attorney's fees.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff is a member of a class which is subject to the provisions of a Nationwide Class Action Settlement Agreement with American Home Products Corporation, approved by the United States District Court for the Eastern District of Pennsylvania. By reason of that Settlement Agreement, plaintiff's causes of action are barred in whole or in part by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, accord and satisfaction, and covenant not to sue and are barred by an injunction entered by that Court.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Answering Defendants reserve the right to amend its Affirmative Defenses.

s/s Janice W. Howe
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Wyeth Pharmaceuticals, Inc.*

Dated: July 23, 2004

CERTIFICATE OF SERVICE

This is to certify that I have this day served the within and foregoing document upon all parties to the above-captioned action by depositing a copy of same in the United States Mail in a properly addressed envelope with sufficient postage affixed thereto to ensure delivery to attorney of record, this 23rd day of July, 2004.

s/s Janice W. Howe

Janice W. Howe

*Counsel for Defendants Wyeth
and Wyeth Pharmaceuticals, Inc.*